K033631

DEC 15 2003

(5)

Section 3
Coatest Factor VIII
510(k) Summary (Summary of Safety and Effectiveness)

Submitted by:

Instrumentation Laboratory Company
113 Hartwell Avenue
Lexington, MA 02421
Phone: 781-861-4467
Fax: 781-861-4207

Contact Person:

Carol Marble, Regulatory Affairs Director
Phone: 781-861-4467 / Fax: 781-861-4207

Summary Prepared:

November 18, 2003

Name of the Device:

Coatest Factor VIII (Modified)

Classification Name:

864.7290 Factor Deficiency Test Class II
81GGP Test, Qualitative and Quantitative Factor Deficiency

Identification of predicate device:

K833892 Coatest Factor VIII

Description of the modified device:

Coatest Factor VIII (K833892) was modified to substitute the natural porcine phospholipids in the Phospholipid reagent with synthetic phospholipids. This modification does not alter the fundamental scientific technology of the device or its intended use for the photometric determination of Factor VIII activity in citrated plasma.

Statement of Technological Characteristics of the Device Compared to Predicate Device:

The modified Coatest Factor VIII is substantially equivalent in performance, intended use, safety and effectiveness to the currently marketed Coatest Factor VIII.

Summary of Performance Data:

Within run and between run precision assessed over multiple runs in the low and high ranges using two levels of control plasma gave the results below:

Range	Control Level	n	Mean % FVIII	Within Run %CV	Between Run %CV
Low	Low	90	14.4	1.5	2.3
High	Normal	89	81.8	1.4	2.4

The following results were obtained in a method comparison study comparing the current legally marketed Coatest Factor VIII to the modified Coated Factor VIII:

n	Slope	Intercept	r	Sample Range
156	1.002	0.365	0.985	1.2 to 147 % FVIII

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 15 2003

Ms. Carol Marble
Regulatory Affairs Director
Instrumentation Laboratory Company
101 Hartwell Avenue
Lexington, MA 02421-3125

Re: k033631
Trade/Device Name: Coatest Factor VIII (Modified)
Regulation Number: 21 CFR 864.7290
Regulation Name: Factor Deficiency Test
Regulatory Class: Class II
Product Code: GGP
Dated: November 18, 2003
Received: November 19, 2003

Dear Ms. Marble:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K033631

Device Name: Coatest Factor VIII (Modified)

Indications for Use:

Coatest Factor VIII was modified to substitute the natural porcine phospholipids in the Phospholipid reagent with synthetic phospholipids. This modification does not alter the fundamental scientific technology of the device or its intended use for the photometric determination of Factor VIII activity in citrated plasma.

For *in vitro* diagnostic use.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K033631

Prescription Use ✓ **OR** Over-The-Counter Use _____
(Per 21 CFR 801.019)